DETAILED ACTION

Response to Amendment

1. The amendment to the claims filed January 14, 2010 is acknowledged by examiner and has been entered. Claims 1 and 16 have been amended. Claims 1-17 and 40 are pending examination on the merits.

Response to Arguments

2. Applicant's arguments, see pg.2, filed January 14, 2010, with respect to claims 1-17 and 40 have been fully considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-17 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Onodera et al. (US 5,407,581).

Regarding claims 1, 10, 11, and 40 Onodera et al. discloses a filter medium for treating a blood material. (See Col 1, lines 8-10) Onodera et al. discloses the surface of the porous element of the filter medium can be modified with a compound by conventional

techniques, such as covalent bonding or ionic bonding, radiation-graft copolymerization or plasma treatment, physical adsorption, embedding, or precipitate immobilization. (See Col 15, lines 64-68) Onodera et al. discloses in addition to the negative functional groups, positive functional groups and/or nonionic functional groups may coexist at or on a surface portion of the filter medium. Examples of nonionic functional groups include: nonionic hydrophilic functional groups, such as a polyethylene glycol chain. (See Col 11, lines 60-68 and Col 12, lines 1-15) Therefore, examiner notes that Onodera et al. anticipates the use of cationic, anionic, and/or nonionic polymers for use with the filter medium. (See Col 12, lines 50-68 and Col 16, lines 9-12 and 35-40) Onodera et al. discloses the filter medium may also be a hollow fiber. (See Col 4, all) While applicant does not use the term "precursor" in the instant specification, examiner notes that applicant discloses in terms of, for example, high processing efficiency, the hollow fiber membrane type is preferable. (See [0020] instant specification) As such, examiner notes that Onodera et al. discloses a modified substrate comprising a hydrophilic polymer as claimed by applicant being covalently bonded to a precursor substrate.

Further regarding claims 1 and 10 examiner notes that Onodera et al. discloses that the compounds having hydrophilic nonionic functional groups as well as the negative charge-containing monomers that coexist on the surface are preferably provided by radiation-grafting. Therefore, one of ordinary skill in the art would expect that less than 15 weight percent of the hydrophilic polymer would not be covalently bonded to the surface since covalent bonding is taught to be a preferred method for providing the hydrophilic

polymer to the surface. One of ordinary skill in the art would further expect that 0.5 mg/m^2 or less of the hydrophilic polymer would not be bonded since Onodera discloses that it is favorable to have the substrate and hydrophilic polymer covalently bonded.

Finally, Onodera et al. discloses it is further preferred that the positive functional groups for the surface of the membrane be those which are less likely to adsorb heparin thereon, because heparin is generally used as an anticoagulant for blood material. (See Col 12, lines 20-24) Therefore, it would have been expected for the blood platelets to not adhere to the membrane since Onodera discloses using heparin as an anticoagulant for the filtered blood. (See Col 3, lines 25-30)

Regarding claims 2-5, examiner maintains the position as set forth above. Further, examiner notes that this claim is directed to process steps for obtaining the modified substrate. As the modified substrate of Onodera et al. has been shown to comprise the same materials and structure as that of applicant, it is assumed that the prior art modified substrate can be obtained in the same manner as that claimed by applicant. Further, applicant is reminded that the patentability of a product does not depend on it's method of production. Therefore, the use of an aqueous solution of the hydrophilic (and a solution containing an antioxidant) is deemed moot since the limitations are again directed to a method of producing the modified substrate. Finally, examiner notes that claim 1 from which claim 2 depends does not recite that the hydrophilic polymer is in solution at all.

Regarding claim 6, as set forth above one of ordinary skill in the art would expect that less than 15 weight percent of the hydrophilic polymer would not be covalently bonded to the surface since covalent bonding is taught to be a preferred method for providing the hydrophilic polymer to the surface. Applicant discloses the surface hydrophilic polymer ratio is a parameter representing the degree of hydrophilicity on the surface of the modified substrate. (See [0017] instant specification) Onodera et al. discloses although any functional groups of the above examples can coexist in the filter medium, nonionic hydrophilic functional groups or chains having these hydrophilic groups are preferred because those groups or chains have excellent effects especially on filter media for removing leukocytes. (See Col 60-68 and Col 12, lines 1-15) Therefore, one of ordinary skill in the art would also expect that the surface hydrophilic polymer ratio of the Onodera modified substrate is at least 20 weight percent.

Regarding claims 7-9 and 12, examiner maintains the position as set forth above. (See Col 11, lines 60-68 and Col 12, lines 1-15) Onodera et al. discloses examples of positive functional groups include ethyleneimine, and oligomers and polymers which have any of the above-mentioned monomers as monomer units thereof. (See Col 12, lines 50-68) Examiner therefore equates the use of ethyleneimine polymers of Onodera et al. to cationic hydrophilic polymers. (See [0028] instant specification) Onodera et al. discloses although any functional groups of the above examples can coexist in the filter medium, nonionic hydrophilic functional groups or chains having these hydrophilic groups are

preferred because those groups or chains have excellent effects especially on filter media for removing leukocytes. (See Col 60-68 and Col 12, lines 1-15) With further respect to claim 9, Onodera et al. further discloses when the substrate is used for an adsorptive filter membrane, the substrate may comprise a negatively charged ligand such as dextran sulfate. (See Col 35, lines 52-59 and Col 36, lines 67-68 and Col 38, lines 20-23) Applicant discloses an anionic polymer such as dextran sulfate may be used. (See [0028]) As such, examiner notes that Onodera anticipates a modified substrate having a plurality of hydrophilic polymers thereon including cationic, nonionic, and/or anionic hydrophilic polymers. Examiner notes that dextran sulfate is also disclosed by applicant as being a polymer derived from the living body. (See [0030] instant specification)

Regarding claim 13, as the modified substrate of Onodera et al. has been shown to comprise the same materials and structure as that of applicant, it is assumed that the prior art modified substrate can function in the same capacity as that claimed by applicant with respect to the adsorptivity of interleukin-6. Further, examiner notes that Onodera et al. discloses an apparatus containing the adsorptive filter membrane which can be used to remove interleukin from a blood material. (See Col 49, lines 22-35)

Regarding claim 14, examiner notes that applicant is not explicit to a particular polyalkylene glycol. As such, it is assumed that all polyalkylene glycols would have a bonding density in the range as claimed by applicant. Onodera et al. discloses in addition to the negative functional groups, positive functional groups and/or nonionic functional

groups may coexist at or on a surface portion of the filter medium. Examples of nonionic functional groups include: nonionic hydrophilic functional groups, such as a polyethylene glycol chain, an amide group, and a polyether chain (such as propylene glycol), which are effective for improving hydrophilic properties of the filter medium. (See Col 11, lines 60-68 and Col 12, lines 1-15) Therefore, the limitation is met by the prior art.

Regarding claim 15, applicant discloses when the substrate is used as a medical substrate for adsorbing and removing a cytokine such as IL-6, the substrate is preferably composed of a hydrophobic polymer because such a polymer has a high adsorbing performance. Because of its high adsorbing performance, polymethylmethacrylate is particularly preferable. (See [0027]) Onodera et al. discloses examples of materials to be used for preparing polymeric, porous element of the filter medium include polymeric compounds which are obtained by polymerization of methacrylate derivatives, such as methyl methacrylate. (See Col 15, lines 6-15)

Regarding claim 16 examiner maintains the position as set forth above for claims 1, 13, and 15. The claimed modified substrate is anticipated by the prior art reference.

Regarding claim 17, Onodera et al. discloses the filter membrane is designed for use in separating an undesired substance from whole blood or plasma. (See Col 3, lines 25-30) Onodera et al. discloses the filter medium may comprise a polymeric, porous element selected from a filter fabric, a porous article, and a porous membrane. The filter medium

may also be a hollow fiber. (See Col 4, all) While applicant does not use the term "precursor" in the instant specification, examiner notes that applicant discloses in terms of, for example, high processing efficiency, the hollow fiber membrane type is preferable. (See [0020] instant specification) Therefore, Onodera et al. anticipates a precursor substrate.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-17 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onodera et al. (US 5,407,581)..

Regarding claims 1, 10, 11, and 40 Onodera et al. discloses a filter medium for treating a blood material. (See Col 1, lines 8-10) Onodera et al. discloses the surface of the porous

element of the filter medium can be modified with a compound by conventional techniques, such as covalent bonding or ionic bonding, radiation-graft copolymerization or plasma treatment, physical adsorption, embedding, or precipitate immobilization. (See Col 15, lines 64-68) Onodera et al. discloses in addition to the negative functional groups, positive functional groups and/or nonionic functional groups may coexist at or on a surface portion of the filter medium. Examples of nonionic functional groups include: nonionic hydrophilic functional groups, such as a polyethylene glycol chain. (See Col 11, lines 60-68 and Col 12, lines 1-15) Examiner notes that Onodera et al. teaches the use of cationic, anionic, and/or nonionic polymers for use with the filter medium. (See Col 12, lines 50-68 and Col 16, lines 9-12 and 35-40) Onodera et al. discloses the filter medium may also be a hollow fiber. (See Col 4, all) While applicant does not use the term "precursor" in the instant specification, examiner notes that applicant discloses in terms of, for example, high processing efficiency, the hollow fiber membrane type is preferable. (See [0020] instant specification) As such,

Further regarding claims 1 and 10 examiner notes that because the polymer is being immobilized on the surface of the porous element, one of ordinary skill in the art would have been easily motivated to minimize the amount of unbonded material thereby improving the functionality of the membrane to treat blood material. (See Col 2, lines 15-25)

Regarding the number of adhered blood platelets, Onodera et al. discloses it is preferred that the positive functional groups for the surface of the membrane be those which are

less likely to adsorb heparin thereon, because heparin is generally used as an anticoagulant for blood material. (See Col 12, lines 20-24) As such, it would have been obvious to one of ordinary skill in the art to minimize the number of adhered human blood platelets such as claimed by applicant since it is the goal of Onodera et al. to utilize the modified substrate as a filter membrane designed for use in separating an undesired substance from whole blood or plasma. (See Col 3, lines 25-30) Therefore, it would be beneficial for the membrane to not adhere blood platelets which would block the porous membrane from filtering out the undesired substance from the blood.

Regarding claims 2-5, examiner maintains the position as set forth above. Further, examiner notes that this claim is directed to process steps for obtaining the modified substrate. As the modified substrate of Onodera et al. has been shown to comprise the same materials and structure as that of applicant, it is assumed that the prior art modified substrate can be obtained in the same manner as that claimed by applicant. Further, applicant is reminded that the patentability of a product does not depend on it's method of production. Therefore, the use of an aqueous solution of the hydrophilic (and a solution containing an antioxidant) is deemed moot since the limitations are again directed to a method of producing the modified substrate. Finally, examiner notes that claim 1 from which claim 2 depends does not recite that the hydrophilic polymer is in solution at all.

Regarding claim 6, as set forth above one of ordinary skill in the art would expect that less than 15 weight percent of the hydrophilic polymer would not be covalently bonded to the surface since covalent bonding is taught to be a preferred method for providing the hydrophilic polymer to the surface. Applicant discloses the surface hydrophilic polymer ratio is a parameter representing the degree of hydrophilicity on the surface of the modified substrate. (See [0017] instant specification) Onodera et al. discloses although any functional groups of the above examples can coexist in the filter medium, nonionic hydrophilic functional groups or chains having these hydrophilic groups are preferred because those groups or chains have excellent effects especially on filter media for removing leukocytes. (See Col 60-68 and Col 12, lines 1-15) Therefore, one of ordinary skill in the art would also expect that the surface hydrophilic polymer ratio of the Onodera modified substrate is at least 20 weight percent.

Regarding claims 7-9 and 12, examiner maintains the position as set forth above. (See Col 11, lines 60-68 and Col 12, lines 1-15) Onodera et al. discloses examples of positive functional groups include ethyleneimine, and oligomers and polymers which have any of the above-mentioned monomers as monomer units thereof. (See Col 12, lines 50-68) Examiner therefore equates the use of ethyleneimine polymers of Onodera et al. to cationic hydrophilic polymers. (See [0028] instant specification) Onodera et al. discloses although any functional groups of the above examples can coexist in the filter medium, nonionic hydrophilic functional groups or chains having these hydrophilic groups are preferred because those groups or chains have excellent effects especially on filter media

for removing leukocytes. (See Col 60-68 and Col 12, lines 1-15) With further respect to claim 9, Onodera et al. further discloses when the substrate is used for an adsorptive filter membrane, the substrate may comprise a negatively charged ligand such as dextran sulfate. (See Col 35, lines 52-59 and Col 36, lines 67-68 and Col 38, lines 20-23) Applicant discloses an anionic polymer such as dextran sulfate may be used. (See [0028]) As such, examiner notes that Onodera anticipates a modified substrate having a plurality of hydrophilic polymers thereon including cationic, nonionic, and/or anionic hydrophilic polymers. Examiner notes that dextran sulfate is also disclosed by applicant as being a polymer derived from the living body. (See [0030] instant specification)

Regarding claim 13, as the modified substrate of Onodera et al. has been shown to comprise the same materials and structure as that of applicant, it is assumed that the prior art modified substrate can function in the same capacity as that claimed by applicant with respect to the adsorptivity of interleukin-6. Further, examiner notes that Onodera et al. discloses an apparatus containing the adsorptive filter membrane which can be used to remove interleukin from a blood material. (See Col 49, lines 22-35)

Regarding claim 14, examiner notes that applicant is not explicit to a particular polyalkylene glycol. As such, it is assumed that all polyalkylene glycols would have a bonding density in the range as claimed by applicant. Onodera et al. discloses in addition to the negative functional groups, positive functional groups and/or nonionic functional groups may coexist at or on a surface portion of the filter medium. Examples of nonionic

functional groups include: nonionic hydrophilic functional groups, such as a polyethylene glycol chain, an amide group, and a polyether chain (such as propylene glycol), which are effective for improving hydrophilic properties of the filter medium. (See Col 11, lines 60-68 and Col 12, lines 1-15) Therefore, the limitation is met by the prior art.

Regarding claim 15, applicant discloses when the substrate is used as a medical substrate for adsorbing and removing a cytokine such as IL-6, the substrate is preferably composed of a hydrophobic polymer because such a polymer has a high adsorbing performance. Because of its high adsorbing performance, polymethylmethacrylate is particularly preferable. (See [0027]) Onodera et al. discloses examples of materials to be used for preparing polymeric, porous element of the filter medium include polymeric compounds which are obtained by polymerization of methacrylate derivatives, such as methyl methacrylate. (See Col 15, lines 6-15)

Regarding claim 16 examiner maintains the position as set forth above for claims 1, 13, and 15. The claimed modified substrate is anticipated by the prior art reference.

Regarding claim 17, Onodera et al. discloses the filter membrane is designed for use in separating an undesired substance from whole blood or plasma. (See Col 3, lines 25-30) Onodera et al. discloses the filter medium may comprise a polymeric, porous element selected from a filter fabric, a porous article, and a porous membrane. The filter medium may also be a hollow fiber. (See Col 4, all) While applicant does not use the term

"precursor" in the instant specification, examiner notes that applicant discloses in terms of, for example, high processing efficiency, the hollow fiber membrane type is preferable. (See [0020] instant specification) Therefore, Onodera et al. anticipates a precursor substrate.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hubbell et al. (US 2002/0128234) discloses multifunctional, polyionic copolymers with molecular architectures and properties optimized for specific applications are synthesized on/or applied to substrate surfaces for analytical and sensing purposes. (See Abstract)

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALTREV C. SYKES whose telephone number is

(571)270-3162. The examiner can normally be reached on Monday-Thursday, 8AM-5PM EST, alt Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 1794

/ACS/
Examiner
3/15/10